DETAILED ACTION

Applicants' arguments, filed 7/2/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections **not** reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Double Patenting:

1) Claims 13, 15 and 18-21 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,750,234. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a method of increasing leptin levels and alleviating a condition alleviatable by increasing leptin levels by administering nicotinic acid or a nicotinic acid ester. The '234 patent defines improved skin epitheliation as a condition alleviatable by increasing leptin levels by administering nicotinic acid or a nicotinic acid ester (see col. 5, line 29).

Applicant argues that "the claims of the '234 patent were all patentable over all the references cited in this current action" (see Remarks 7/2/2008 p. 5). This is not convincing for the following reasons: 1) the '234 patent was subject to terminal disclaimer; 2) each application is evaluated on it's own merits; and 3) the conflicting claims, while not identical are not patentably distinct (see rejection reiterated above).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 15 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scivoletto (WO 98/52927) in view of U.S. Patent No. 6337065.

The claims are directed to a method of increasing leptin levels using an effective amount of nicotinic acid or its ester wherein the said amount should be sufficient to increase leptin levels and to alleviate a condition alleviatable by increased leptin levels.

The limitation "skin epitheliation" is interpreted to mean a process where the skin epithelial layer would develop, such as would occur in normal skin homeostasis and remodeling, or healing. See Figure 1 of the current application.

Scivoletto teaches a pharmaceutical composition comprising a therapeutically effective amount of nicotinic acid **or its derivatives** (e.g., nicotinic esters, nicotinamide) to treat skin conditions(e.g., burns, acne, etc.) when the composition is applied topically, see abstract. With respect to the limitation wherein the alkyl chain of said nicotinic acid alkyl ester contains from 1-22 carbon atoms, Scivoletto exemplifies methyl nicotinate (nicotinic acid ester with 1 carbon atom containing unsubstituted alkyl chain) in the patented composition, see pages 3-4. The skin condition (e.g., burns, acne) taught in Scivoletto is a skin wound (the interruption of continuity of any body tissues) and thus, Scivoletto teaches the recited limitation requiring skin epitheliation. Claim 1 also recites the use of nicotinic acid and nicotinic acid esters and their derivatives.

Although Scivoletto is silent about the recited limitation (i.e. increasing leptin level), modulation of leptin level is an underlying biological mechanism wherein the increased leptin levels are naturally occurring and achieved when the nicotinic acid or its ester is applied to treat skin wounds (e.g. burns or acne). Thus, this said biological mechanism (i.e., increasing leptin levels) via administering an effective amount of nicotinic acid or its esters for treating skin wounds, is considered to be inherent feature and the claims are anticipated. In the absence of a showing that these mechanisms of action are not present in the treatment of Scivoletto, one skilled in the art would have considered such properties (the increase of leptin) to be inherent in the application of the nicotinic acid ester.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to

"prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.,* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

While Scivoletto does not specify the instantly claimed derivatives, U.S. Patent No. 6337065 (the '065 patent) teaches such derivatives of nicotinic alkyl esters containing alkyl chains containing 8-30 carbon atoms, including octylnicotinate (8 carbons in the alkyl chain), tetradecylnicotinate (14 carbons in the alkyl chain) and octadecylnicotinate (18 carbons in the alkyl chain). See: col. 4, line 51- Col. 5, line 20; Fig. 13). The reference teaches that these agents are useful in enhancing dermal and epidermal skin deterioration and damage (see abstract).

As Scivoletto teaches the use of nicotinic acids and nicotinic alkyl esters and their derivatives for treatment of skin disorders (including improvement of skin epitheliation), it would have been obvious to one of ordinary skill in the art to use the derivatives taught by the '065 patent. One would have been motivated to use the nicotinic acid and nicotinic alkyl esters derivatives taught by the '065 patent having been taught that they are also used in treating skin deterioration disorders.

Although Scivoletto teaches nicotinic acid or nicotinic acid esters, Scivoletto fails to mention a combination of nicotinic acid and at least one nicotinic ester, or a mixture of more than one nicotinic acid esters required by the instant claim 21.

As mentioned above, Scivoletto teaches that nicotinic acid or nicotinic acid derivatives such as nicotinic acid esters is used effectively in the treatment of skin wound (e.g., burns or acne), thus including skin epithiliation.

However, the minor variations including the selection of optimal mixture among the effective species in order to determine the most effective treatment is well within the purview of the skilled artisan, and is obvious. One would have been motivated to make such modification (i.e., to substitute nicotinic acid, nicotinamide or nicotinic acid ester with a mixture of nicotinic acid and nicotinic acid esters, or a mixture of more than one nicotinic acid esters) because the mixture of different compounds would have counteracted the undesired side effect while maintaining the therapeutic efficacy. Modification of the pure nicotinic acid molecules is well known in the art, resulting in various derivatives thereof (e.g. nicotinamide, nicotinic esters such as methyl nicotinate) in order to reduce the side effects. Because each compound has different chemical properties (e.g., polarity, solubility, different degree of efficacy due to different reactivity against receptors), the efficacy would be beneficially modified when they mix these compounds. Thus one would have motivate to use the mixture of these compounds to maximize the therapeutic effectiveness with reasonable expectation of success because each compound has been known to be effective species for treating skin wounds, and thus skin epilthiliation.

One would have been motivated to combine these references and make the modification because they are drawn to the same technical field (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which with which the application is concerned. See MPEP § 2141.01(a).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is 571-272-9032. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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